

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,

v.

(1) STRYKER BIOTECH, LLC,

(2) MARK PHILIP,

(3) WILLIAM HEPPNER,

(4) DAVID ARD and

(5) JEFFREY WHITAKER,

Defendants.

Criminal No.: 09-CR-10330-GAO

**GOVERNMENT’S OPPOSITION TO STRYKER CEO STEPHEN MACMILLAN’S
MOTION TO QUASH TRIAL SUBPOENA OR, IN THE ALTERNATIVE
FOR RELIEF FROM TESTIFYING PRIOR TO JANUARY 16, 2012**

Introduction

The United States hereby opposes Stryker Corporation’s CEO Stephen MacMillan’s motion to quash his trial subpoena. First, as to the alternative relief he seeks, postponing his testimony until January 16, 2012, the government has repeatedly told his counsel that it would accommodate his schedule in that manner, if that would obviate the need for any motion practice. Second, Mr. MacMillan is indeed an important witness in this case – important enough that the government advised his counsel that it planned to call him as one of its first witnesses at trial. From the time the United States interviewed Mr. MacMillan in April 2009 during the government investigation, to the time it issued him a trial subpoena in May 2011, to the time it advised his counsel in writing on October 24, 2011 that the government was “planning to call your client Stephen MacMillan as one of our first witnesses at trial [,] we are letting you know

now so that you and he can arrange your schedules to be available the week of January 9, 2012,” to the time it recently communicated a willingness to accommodate Mr. MacMillan’s schedule and call him the week of January 16, 2012, the government has been steadfast in its good faith pursuit of testimony from Mr. MacMillan to assist in proving the charges in this case. It is well established that the public “has a right to every man’s evidence” and this principle applies to Mr. MacMillan as well as to all the other anticipated witnesses in this trial. United States v. Bryan, 339 U.S. 323, 331 (1950).

Background and Chronology

MacMillan levels charges against the government of “gamesmanship and leverage” for some unspecified “tactical advantage.” MacMillan Motion at 1. As the background and chronology below demonstrate, MacMillan is the only one playing games.

At all relevant times to the Superseding Indictment, MacMillan was the President and Chief Executive Officer of Stryker Corporation, the parent company of the corporate defendant Stryker Biotech. While his motion attempts to minimize his managerial role with respect to Stryker Biotech, and Stryker Biotech’s former president defendant Mark Philip, MacMillan’s role was significant.

The chronology of MacMillan’s involvement in this investigation is as follows:

- April 24, 2009 – the government interviewed MacMillan during its investigation that led to the instant charges. The interview covered a range of topics relevant to the Superseding Indictment, such as the types of “regular” involvement MacMillan had with Stryker Biotech and defendant Philip, including monthly “highlights” memos he received from Stryker

Biotech, compliance differences between Stryker Biotech and other Stryker divisions, Stryker Biotech's products OP-1 and Calstrux, Stryker Biotech's interactions with the FDA, MacMillan's decision to halt sales of OP-1 Putty in February 2008, and Philip's termination from Stryker Biotech, among other topics.

- May 3, 2011 – the government served a trial subpoena on MacMillan.
- October 24, 2011 – the government advised MacMillan's counsel in writing: "We are planning to call your client Stephen MacMillan as one of our first witnesses at trial. We are letting you know now so that you and he can arrange your schedules to be available the week of January 9, 2012." Exhibit A attached.

- November 11, 2011 – in response to various telephonic communications with MacMillan's counsel in which he took no firm position on the subject of MacMillan's appearance, the government advised MacMillan's counsel in writing: "At this week's hearing, Judge O'Toole set Dec. 7 as the deadline for the parties to file motions in limine. If you plan to file one on S. MacMillan, we'd ask that you do it by that date too." Exhibit B attached.

- November 17, 2011 – in response to more equivocal communications about various positions he might take on MacMillan's behalf, the government advised MacMillan's counsel in writing: "Given that it is our plan to call MacMillan the first week of trial, please let us know as soon as possible if he will be invoking his 5th Amendment rights, and if so, please so state in writing." Exhibit C attached.

- December 6, 2011 – counsel for MacMillan provided the government a list of MacMillan's scheduled activities for the week of January 9, 2012. The government promptly

informed counsel that it would agree to call him the week of January 16, 2012, if delaying his appearance until that week would avoid motion practice.

- December 12, 2011 – counsel for MacMillan asked the government if it would consider a stipulation of testimony from MacMillan as opposed to his live testimony. The government promptly informed him that it would not agree to a stipulation.
- December 13, 2011 – counsel representing both Stryker Corporation and Stryker Biotech called and asked to meet with the government, and at the meeting held later that day asked the government to consider not calling MacMillan; a request the government declined at that meeting.

This chronology demonstrates that the government has been steadfast about calling MacMillan to testify, has been forthright about that intention, and has been courteous in both providing early notice of his anticipated trial testimony and also communicating a willingness to accommodate MacMillan’s schedule. In the face of that treatment, the government has been confronted with dilatory tactics and misdirection.

MacMillan’s Testimony is Relevant

MacMillan has apparently arrogated to himself the determination of what evidence is relevant to the government’s case in chief. He does so without alluding to FRE 401, which defines relevant evidence as “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” The First Circuit has described this threshold for relevance as “very low,” United States v. Nason, 9 F.3d 155, 162 (1st Cir. 1993), and “not-too-hard-to-meet,”

United States v. Polanco, 634 F.3d 39, 44 (1st Cir. 2011). The government, here, easily surmounts this threshold with respect to MacMillan.

Despite his efforts to minimize his involvement with Stryker Biotech and its products, it is apparent that MacMillan has much to offer by way of relevant testimony in this case. While the government is not obliged to, and will not, provide him and the defendants with a detailed description of its direct examination topics, a few noteworthy items are facially apparent even from the government's recently filed exhibit list. For example, in his own words at his presentation at the 2005 Stryker Biotech National Sales Meeting in January 2005, MacMillan made plain that OP-1 was one of the main reasons he joined Stryker Corporation:

And I want to tell you first and foremost one of the real things that brought me to Stryker in addition to John's absolute perseverance and everything else was the fact that we had OP-1 and we had this Biotech division. Because as I look at the future of healthcare, I really think it's about medical devices and biotech are going to be the stars of the next 20 to 50 years. And I was so intrigued that Stryker, a pure device company, had had the foresight to start to bet on a product in biotech.

Proposed Government Exhibit 283.

Over the next three years, MacMillan maintained ultimate oversight over Stryker Biotech in his capacity as CEO of the corporate parent Stryker Corporation, and his activities included review and approval of Stryker Biotech's annual sales budgets, review of major capital expenditures by Stryker Biotech, review of monthly "highlight" memos from Stryker Biotech (prepared by defendant Philip) advising him of various "accomplishments" and "concerns" (which some months included concerns about the "HDE cap"), periodic on-site visits to Stryker Biotech in Hopkinton, Massachusetts for management updates (which included an update on "HDE cap" issues), and personal interaction with executives at Stryker Biotech. MacMillan

personally made decisions regarding Stryker Biotech from January to March 2008 on a number of issues, including his directive to halt sales of OP-1 Putty in February 2008 based on concerns that Stryker Biotech had sold OP-1 Putty to more than 4000 patients during the year. Further, in 2008 MacMillan personally attended a meeting with representatives from the FDA to discuss the Stryker Biotech compliance shortcomings that led to its receipt of an FDA Warning Letter.

Despite his protestations to the contrary, MacMillan had substantial interest and involvement with Stryker Biotech and its products; as he puts it, OP-1 was one of the main reasons he took the job as CEO of Stryker. His interest and alignment with Stryker Biotech is evident from a range of his conduct, some of which is summarized above, but also from the fact that in 2007, a portion of his bonus was tied, as reflected in the board minutes of Stryker Corporation, to his efforts to “[d]efine a clear pathway for the approval of OP-1 by the FDA.” MacMillan’s claims that he has no relevant evidence are also undermined by the Consolidated Proposed Exhibit List (Docket Entry No. 218) filed by the defendants the same day as MacMillan’s motion. That exhibit list contains a proposed Exhibit 531, an email from MacMillan to Philip regarding “Biotech Spine PMA New Data Acquisition,” and a proposed Exhibit 798, another email from MacMillan to Philip regarding “Biotech PMA Update.”

In short, MacMillan had a variety of personal involvement with Stryker Biotech and its executives and its products during the period of the charged conspiracy. His testimony is relevant to this case under FRE 401.

There is No Basis Under FRCP 17 To Quash MacMillan's Subpoena.

It is not altogether clear that FRCP 17 provides a mechanism to quash a subpoena for testimony (as opposed to a subpoena for documents). The text of FRCP 17(c)(2) appears directed only at subpoenas for documents and objects. Even if it does apply to testimony, as some courts have interpreted it, the rule articulates a standard of "unreasonable or oppressive." MacMillan cannot and does not meet this standard. By its subpoena, the government seeks testimony that is clearly relevant to the trial, some of which emanates from MacMillan's interview with the government during its investigation. Further, by its early notice and willingness to engage in scheduling courtesies, the government's conduct can in no way be characterized as oppressive toward MacMillan.

The cases cited by MacMillan are inapposite. One case is about whether a district court could adopt a local rule requiring prosecutors to seek prior judicial approval before serving a grand jury subpoena on an attorney, for the purpose of obtaining evidence about the attorney's clients. United States v. Klubock, 832 F.2d 664 (1st Cir. 1987). Another case involves quashing a trial subpoena of Department of Justice employees when the party issuing the subpoena had failed to comply with the DOJ regulations for subpoenaing witnesses that "have been held to be valid and mandatory." United States v. Wallace, 32 F.3d 921, 929 (5th Cir. 1994). Yet another case involves a defendant who was a scrimshander on Nantucket accused of illegally importing and smuggling whale bones into the United States. Despite having absolutely no involvement or contact with them, he issued trial subpoenas seeking the attendance by the Secretary of the

Interior and the Secretary of the Department of Homeland Security. United States v. Manghis, 2010 WL 349583 (D. Mass.). Judge Gertner allowed the government's unopposed motion to quash. Id. United States v. Nivica, 887 F.2d 1110, 1118 (1st Cir. 1989) is completely off point as it affirms the district court's unwillingness to issue subpoenas under a different part of the rule, FRCP 17(b), for an indigent defendant to a host of witnesses that the court deemed, according to the applicable standard in the rule, not "necessary to an adequate defense."

Finally, MacMillan cites (twice) to the Oliver North criminal case in which trial subpoenas for testimony were issued to both then-President George Bush and former President Ronald Reagan. United States v. North, 1989 WL 9087 (D.D.C. 1989). MacMillan points out that the district court quashed the subpoena as to President Bush, finding that Colonel North had made no showing that he had any "specific information relevant and material to the charges." Id. at *1. He does not point out that the district court did not, in the same opinion, quash the subpoena as to President Reagan. Id. Being president of Stryker Corporation with direct, regular and personal interactions with one of the divisions that makes up Stryker Corporation, namely Stryker Biotech, about some of the very issues present in the Superseding Indictment does not compare to being President of the United States with no direct, regular and personal interactions with Colonel North related to his prosecution arising from the Iran/Contra affair.

None of these cases offer MacMillan any succor. He is not an attorney or an improperly subpoenaed DOJ employee, nor is he in the position of a federal agency head called in the case of some unknown purveyor of smuggled whalebone. Rather, he is the CEO of a company that includes a division that is a defendant in a criminal trial starting on January 9, 2012. And he was

the CEO during all the time identified in the Superseding Indictment and had regular, active, and relevant contact with that division, including with defendant Philip.

It is the government, not MacMillan, that decides how to try its case. Here, for a long time, the government's plan has been to call MacMillan and call him early in its case. Notwithstanding the early notice provided to him, the government has also been willing to accommodate his assertion that he is fully booked the week of January 9 and to call him the week of January 16. See MacMillan's "Certification Pursuant to Local Rule 7.1" (noting the "government expressed a willingness to schedule Mr. MacMillan's appearance during the week of January 16, 2012"). In United States v. Bryan, 339 U.S. 323, 331 (1950), the Supreme Court noted:

Dean Wigmore stated the proposition thus: "For more than three centuries it has now been recognized as a fundamental maxim that the public (in the words sanctioned by Lord Hardwicke) has a right to every man's evidence."

MacMillan may be a busy CEO, but he is a man, like any other, and the jury in this case is entitled to hear from him.

Conclusion

There is no basis for MacMillan's motion to quash and it should be denied and he should be ordered to appear for testimony at trial on January 16, 2012, until he is reached.

Respectfully submitted,
CARMEN M. ORTIZ
United States Attorney

By: /s/ Jeremy M. Sternberg
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Dated: December 23, 2011

Certificate of Service

I hereby certify that the foregoing documents filed through the ECF system will be sent electronically to counsel for each defendant and non-party, including counsel for the non-party movant Stephen MacMillan, who is a registered participant as identified on the Notice of Electronic Filing (NEF).

/s/ Jeremy M. Sternberg
Jeremy M. Sternberg
Assistant U.S. Attorney

Dated: December 23, 2011

EXHIBIT A

From: Sternberg, Jeremy (USAMA)
Sent: Monday, October 24, 2011 2:03 PM
To: 'Peter Gelhaar'
Cc: Noonan, Gregory (USAMA); Winkler, Susan (USAMA)
Subject: S MacMillan

Peter,

We are planning to call your client Stephen MacMillan as one of our first witnesses at trial. We are letting you know now so that you and he can arrange your schedules to be available the week of January 9, 2012.

Jeremy M. Sternberg
Assistant U.S. Attorney
U.S. Attorney's Office
District of Massachusetts

EXHIBIT B

From: Case 1:09-cr-00330-UNA Document 242 Filed 12/23/11 Page 14 of 16
Sent: Friday, November 11, 2011 1:25 PM
To: 'Peter Gelhaar'
Cc: George W. Vien; Winkler, Susan (USAMA); Noonan, Gregory (USAMA)
Subject: RE:

At this week's hearing, Judge O'Toole set Dec. 7 as the deadline for the parties to file motions in limine. If you plan to file one on S. MacMillan, we'd ask that you do it by that date too. If you are not willing to do so by that date, please let us know next week so that we can seek an order from the court.

EXHIBIT C

From: Sternberg, Jeremy (USAMA)
Sent: Thursday, November 17, 2011 9:23 AM
To: 'Peter Gelhaar'
Cc: George W. Vien
Subject: RE: Case 1:09-cr-00330-GAO Document 242 Filed 12/23/11 Page 16 of 16

Peter, As discussed earlier this week, for your witnesses for whom you are requesting statutory immunity for testimony at trial, please provide the following information: (1) date of birth; (2) place of birth; (3) address; and (4) social security number. We are aiming to get the applications out before Thanksgiving.

The people in that category on my list are:

If I've left anyone out, please add. Given that it is our plan to call MacMillan the first week of trial, please let us know as soon as possible if he will be invoking his 5th Amendment rights, and if so, please so state in writing.